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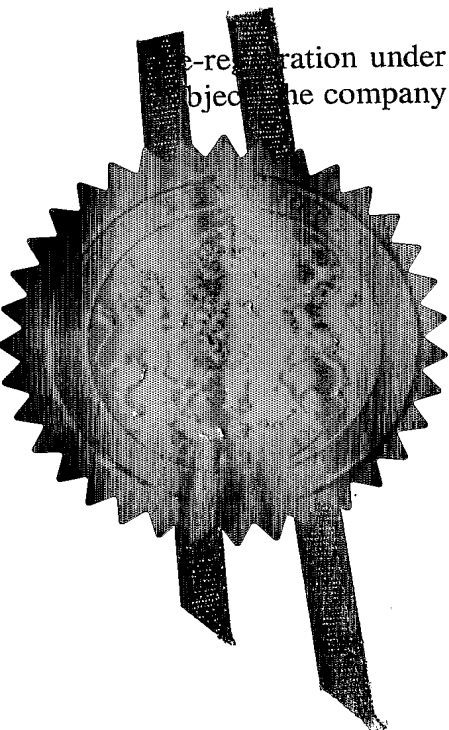
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2252

2. Patent application number

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0328859.4

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Clinical Designs Limited  
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Aldsworth  
Emsworth

Patents ADP number (if you know it)

Hampshire PO10 8QT  
GB

If the applicant is a corporate body, give the country/state of its incorporation

GB

8549466001

4. Title of the invention

Dispenser and Counter

5. Name of your agent (if you have one)

NIGEL BROOKS CPA

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

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| Country | Priority application number (if you know it) | Date of filing (day / month / year) |
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| GB      | NA   | NA                                  |
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DISPENSER and COUNTER

The present invention relates to a dispenser, particularly though not exclusively for dispensing aerosol or powder borne medicaments, and to a counter for  
5 such a dispenser.

I have applied for a number of patents on dispensers for a gaseous, gas borne or droplet substance. In particular, in my prior International Patent Application, PCT/GB98/00770, at least as amended on entry in the European Regional Phase, there  
10 is described and claimed:

A dispenser for a gaseous, gas borne or droplet substance, the dispenser including:

- a body having a mouthpiece with an inhalation/insufflation orifice at its end;
- a junction in the body for a source of gas or evaporable liquid comprising or  
15 containing the said substance (the source being carried by the body); and
- a breath actuatable valve, for controlling the release of said gas or liquid, comprising:
  - a valve inlet connected to the junction;
  - a valve outlet;
  - 20 • a flexible tube extending from the junction, between the inlet and the outlet, for receiving the said gas or liquid, the tube having a portion which is movable between a closed position in which the tube is kinked for closure of the valve and an open position in which the tube is un-kinked for opening of the valve; and
  - a movable member, for moving the movable portion of the tube to control its  
25 kinking, and being movably mounted in the body for movement by the act of inhalation from a rest position towards the orifice – or at least in the direction of air flow through the dispenser;
  - the tube being kinked to an obturating extent when the movable member is in a  
30 rest position and un-kinked when the movable member is moved on inhalation for release of the gas or liquid.

Such a dispenser can loosely be classed as a breath actuated, kink valve dispenser and is referred to herein as "My Earlier Breath Actuated, Kink Valve Dispenser".

5 With such a dispenser, in common with others of my design and other designs, there is advantage to the user in knowing how many doses are left in the reservoir of the substance source, the reservoir typically being an aerosol valve can, the can being an aluminium forging.

10 Two approaches to dose measurement are known.

Firstly, dispensers actuated by depression of the end of the can towards the body of the dispenser body can be provided with electronic counters which sense the number of depressions and count down to indicate exhaustion of the dispenser. This  
15 approach is costly.

A second approach is to provide the source with a transparent reservoir, typically of glass. Existing glass reservoirs have replicated the shape of the prior forged aluminium can. Their shape renders difficult estimation of the number of  
20 doses remaining.

The object of the present invention is to provide dispenser having a receptacle for a counter, the counter being removable from an exhausted dispenser for use with a new dispenser.  
25

Such an arrangement has advantage in the ability of the relatively expensive counter to be re-used with successive dispensers. However, I believe that the following important consideration needs to be addressed:

- The counter should be able to be fitted only to a dispenser that is new and unused.  
30 Failure to ensure this could result in a counter being fitted late to a partially used dispenser, with the result that the dispenser becomes, empty and/or reaches a state of variable dosage when approaching emptiness, before the counter indicates this state. In other words the counter could indicate that there are an appreciable number of doses left when the dispenser is exhausted.

According to one aspect of the invention there is provided a dispenser for a gaseous, gas borne or droplet substance comprising:

- a body having a mouthpiece with an inhalation/insufflation orifice at its end;
- 5 • a source of the substance accommodated on the body;
- a junction in the body for receiving the substance from the source,
  - the source and the junction being arranged to be movable towards each other for release of a substance dose from the source to the junction;
- valve means in the source and/or downstream thereof, for releasing the  
10 substance to the mouthpiece a dose at a time;
- a counter for counting released doses, the counter having:
  - a transducer for detecting dispensing of a dose from the source and/or to  
the mouthpiece;
  - a receptacle on the body for accommodating the counter with its transducer  
15 operatively in contact with the source; and
  - a closure for the receptacle for removably enclosing the counter in the  
receptacle and establishing an abutment for the source or the junction against  
which the one can be held for movement of the other towards the one for dose  
release.

20

According to another aspect of the invention there is provided a dispenser for a gaseous, gas borne or droplet substance comprising:

- a body having a mouthpiece with an inhalation/insufflation orifice at its end;
- a source of the substance accommodated on the body;
- 25 • a junction in the body for receiving the substance from the source;
  - the source and the junction being arranged to be movable towards each other for release of a substance dose from the source to the junction;
- valve means in the source and/or downstream thereof, for releasing the  
substance to the mouthpiece a dose at a time;
- 30 • a receptacle on the body for accommodating a dose counting counter with its  
transducer operatively in contact with the source; and
- a closure for the receptacle for removably enclosing the counter in the  
receptacle and establishing an abutment for the source or the junction against



which the one can be held for movement of the other towards the one for dose release.

It will be noted that the consideration of the counter being fitted only to a new  
5 and unused dispenser is met by the fact that until the closure has been fitted, the abutment is not established and the action which would otherwise result in release of a dose does not do so.

A dose will be released from the source by relative displacement of the source  
10 and the junction towards each other. There will normally be provided a means for moving the junction, with the source being limited in its movement in the body by fitting of the enclosure. With this arrangement, the source will usually have a metering valve and a release valve will be provided downstream of the metering or  
15 both metering and release can be performed by a single valve downstream of the junction. The former of these two arrangements can be embodied as in My Earlier Breath Actuated, Kink Valve Dispenser. Alternatively, as in an older type of dispenser the junction may be located against the abutment with the source being movable towards it and the valve being a metering and release valve in the source.

20 In either of these alternatives, the counter itself may provide the abutment for source or the junction. Alternatively, the closure may be formed to provide the abutment.

I believe that a further important consideration is that:

- 25 • The counter should not be able to be re-inserted into a dispenser from which it has been removed.

Accordingly, the receptacle closure is preferably irremovably connected to the body and provided with a frangible portion through which the counter can be  
30 removed. However, it can be envisaged that the adjustable part of the body may have a frangible portion for release of the counter.

Where the closure provides an abutment for the source or the junction, removal of the counter leaves the dispenser still usable. This may be acceptable in

certain circumstances as an emergency reserve. Where the counter provides the abutment, removal of it renders the dispenser no longer usable. This provides that when the dispenser is indicating via the counter that it is exhausted (in practice to the extent that correct dosage can no longer be relied upon), removal of the counter to a  
5 fresh dispenser prevents unreliable use of the dispenser.

Where the source is fixed or at least allowed only limited movement with the junction being moved towards it, and its abutment provided by the closure or the counter, an adjustable part of the body can be set at an appropriate position for release  
10 of the dose on operation of the junction moving means as disclosed in my prior patent application No. PCT/GB03/001102. To achieve this positioning an adjustable part of the body can be provided with a simulated abutment, set at a determined position relative to a datum in the adjustable part. The datum can be the end of the adjustable part.

15

The receptacle for the counter will normally be provided at the end of the adjustable part – or the equivalent part in a movable source dispenser.

The closure can be a plug fitted into the end of the receptacle to captivate the  
20 counter or a cap over the end of the receptacle. Normally the closure will have a window for viewing the display of the counter.

It is envisaged that, the counter can have an acoustic transducer or a displacement transducer for detecting dose release by a distinctive sound of the  
25 release or by a small movement of the source between its position in which the junction is moved towards it for dose release and its quiescent position. Alternatively, the counter can have a force transducer able to detect urging of the source against the counter when inserted. In whichever form, the counter will preferably have a probe in contact with the source. Conveniently the probe can be arranged to detect removal of  
30 the source from the dispenser and to reset the counter for new use in another dispenser.

The dispenser will normally be able to be used without a counter, either in the case the body having an abutment by fitting a cap over the receptacle with the counter

or in the case of a body without an abutment by fitting a spacer simulating the counter.

According to a third aspect of the invention there is provided a counter for a  
5 dispenser of the invention, the counter being adapted to be accommodated on the  
dispenser, having:

- a display for indicating number of doses consumed or still available to be consumed,
- a transducer for detecting dispensing of a dose and
- 10 • a reset probe activated to reset the counter on its removal from the dispenser.

To help understanding of the invention, various specific embodiments thereof will now be described by way of example and with reference to the accompanying drawings, in which:

15 Figure 1 is an exploded, part sectioned side view of a first dispenser of the invention;

Figure 2 is a scrap, sectional side view of the distal end of the body of the dispenser of Figure 1;

Figure 3 is a similar, non-sectioned side view of the distal end;

20 Figure 4 is an end view of the distal end;

Figure 5 is a view similar to Figure 2 of a dispenser with a variant;

Figure 6 is a side view of the variant of Figure 5;

Figure 7 is a sectional side view of a barrel plug for a second embodiment of  
dispenser of the invention;

25 Figure 8 is a sectional view of a distal end of the barrel of the dispenser of Figure 7;

Figure 9 is a similar view of the plug and a counter fitted to the distal end; and

Figure 10 is a view similar to Figure 1 of a third dispenser of the invention.

30 Referring to Figures 1 to 4, the dispenser there shown has a body 1, with a mouthpiece cover 2, as described in my International Patent Application No. PCT/GB01/03313. Opening of the cover urges a junction member 3 towards a source 4 of a medicament to be released as a dose by pressing a spout 5 of the source inwards

of the source, as is well known in the art. The source is supported by a cap 11 clipped to the end of a source-enclosing barrel 12 with internal splines 10. For this the cap has a splined 13 abutment bush 14 received in the barrel at a determined distance D from the end of the barrel. The barrel is welded 15 to the main part 16 of the body at a position determined by the extension of the source towards the distal end 17 of the barrel when the cover is open, the welding position being determined by a plug 18 simulating the cap and its bush. Such welding is described in more detail in my International Patent Application No. PCT/GB03/001102.

10 Close to the distal end of the barrel, it has a groove 19. The cap has a collar 21 with a lip 22 for engaging in the groove 19. It also has an end disc 23 connecting the bush and the collar and having a central aperture 24 for viewing a display of an electronic counter 25. A central portion 32 of the end disc 23 is frangible with a tear groove 26.

15

In use the counter 24 is received in the cavity 28 formed by the bush 14 and the disc 23, with a can probe 29 in contact with the end 30 of the can. The counter has an acoustic sensor associated with the probe and firmware programmed to recognise the distinctive sound of release of a dose. On such recognition, the display 31 of the counter, visible through the aperture 24, decrements one in the count of doses left available to the user of the dispenser.

On supply of the dispenser and the counter to the user, the counter and the cap are not fitted to the dispenser. The probe is not depressed inwards of the counter, thus the counter is in quiescent state. Fitting of the counter to the recess and the cap to the dispenser brings the probe into firm contact with the can. The counter is initialised and its display shows the full count of doses in the can for example 100. Actuation of the cover 2 releases a dose – on inhalation where the dispenser is breath actuated. As use continues, the count of available dose falls until it reaches zero. The dispenser is exhausted, or at least has reached a remaining quantity of medicament such that dosage is no longer reliable. A rectangular spigot 6 is provided on the base of the body with a size and shape to irrotationally fit the counter viewing aperture 24. The spigot of a fresh dispenser is engaged in the window of the exhausted dispenser. The splines 10,13 of the body barrel and the cap having irrotationally engaged these

members on fitting of the cap, twisting of the two dispensers with respect to each other severs the disc 23 from the rest of the cap. The counter can then be removed. Its probe 29 is no longer depressed and the counter returns to its quiescent mode, until fitted to the new dispenser. The old dispenser can still be used, if this is safe in view  
5 of the uncertainty of the dose, as an emergency reserve, with the abutment for the source on the bush 14 still being available.

In the variant shown in Figures 5 & 6, the cap 111 does not have a bush against which the end of the source abuts. Rather, it is the counter against which the  
10 source abuts, but with a small free movement  $l$ . This will be explained further in the next paragraph. The cap is closed with an end disc 123 having a window 124 through which the count of the counter is visible. Again the cap is secured by a collar 121 with a lip 122 engaging in a groove 119 in the barrel of the body. Internally, the collar is provided at mid-height with a tear groove 126. The lower, tearable portion  
15 151 of the collar has peripheral discontinuity 152 and a graspable protrusion 153 continuous with the tearable portion on its side opposite from the discontinuity.

In manufacture, the barrel is set on the body such that the source releases a dose when the end of the source is at a distance  $L$ , the thickness of the counter, from  
20 the end of the barrel. The throw of the cam mechanism (not shown) in the dispenser for moving the junction member towards the source is greater than the stroke of the spout into the source, so that in the quiescent state of the dispenser, a spring (not shown) in the counter urging its probe 130 towards the source returns the source to be separated from the counter by the distance  $l$ . The counter counts on depression of the  
25 probe through this distance  $l$  on operation of the cam mechanism. Further it has another probe position, further extended from the counter body in which it resets to its quiescent state.

For initial use, the counter is inserted in the end of the barrel and the cap is  
30 placed over the counter, clipping onto the barrel via the lip 122 and the groove 119. The probe is moved towards the body of the counter by contact with the source, resetting the counter from its quiescent state to the full count of doses. Use of the dispenser moves the source up through the displacement  $l$ , with the count decrementing one dose on each use. On exhaustion of the source, the tear strip 151 is

torn off, allowing the counter to be removed to a fresh dispenser. The old dispenser can still be used in an emergency, by manual pressure on the end of the source.

In a further non-illustrated variant, the counter has an integral load cell, for  
5 detecting release by detecting the force applied from the source to the counter on dispensing of a dose from the source. The force is that necessary to displace the spout inwards of the can. The counter still retains its probe as a detector of whether it is installed in a dispenser or not, i.e. whether it is in a quiescent or counting mode.

10 Turning on to the embodiment of Figures 7, 8 & 9, the end of the barrel 312 has step 350 out in diameter to accommodate an end plug 351 as opposed an end cap of the other embodiment and variants. The enlarged portion 352 of the barrel has a plain bore orifice 353, an annular lip 354 and a longitudinally splined length 355 between the step 350 and the lip 354. An end disc 356 of the plug has a rectangular  
15 aperture 357 for viewing a counter 324 accommodated within a sleeve 358 of the plug. Adjacent the end disc, the sleeve has a tear groove 359, beyond which complementary splines 360 extend to the end of the plug. It should be noted that the sleeve is thicker radially than the radial dimension of the step.

20 The barrel is set with the internal end face 361 of the step level with the end of the can 303 in its valve depressed, dose-release position. When the plug is inserted into the barrel, with a counter accommodated in it, the splines 355,359 inter-engage with the end of the splines on the plug fitting under the lip 354 and end face 362 of the sleeve 358 abutting the step face 361. The can abuts against the plug, end face  
25 362, level with the barrel end face 361.

The counter counts as in the variant of the previous embodiment shown in Figures 5 & 6, i.e. by displacement of its probe. When the dispenser is exhausted, a  
30 complementary formation (not shown) on the bottom of a fresh dispenser is engaged in the rectangular aperture 357 and twisted. Twisting of the plug is resisted by the spline and the sleeve tears at the groove 359. The end disc and the counter can then be removed, and the counter fitted to the fresh dispenser with a fresh end plug.

Turning on to the embodiment of Figure 10, the dispenser comprises a body 401, with a mouthpiece 402 and a junction member 403 for a medicament source 404. The body has a base 475, with a depending annulus 476 and an upstanding internal tube 477 for slidably accommodating the junction, which is retained by a lip 478 on the inside of the tube and engages with a collar 479 to prevent the junction member being removed from the dispenser in the direction of the source 404. The junction member and the internal tube are of complementary shape, typically rectangular, to ensure that the nozzle on the junction member remains directed out of the mouthpiece 402.

10

A counter 425 is retained within the annulus 476 by an end disc 423 with a counter window 424. The end disc is held on by an integral collar 421 with a lip 422 engaging in a groove 419. The end disc is removable by severing along a groove 426 with a non-shown grippable member. These features are essentially as in the previous embodiment.

15

The junction member has a recess 480 for a probe 429 of the counter. The counter counts in the manner of the other embodiments and can be moved to a fresh counter in like manner. Before a counter is fitted and after it is removed, the dispenser cannot be used as the junction is not fixed to resist depression of the source and cause the spigot to be moved inwards of the source.

20

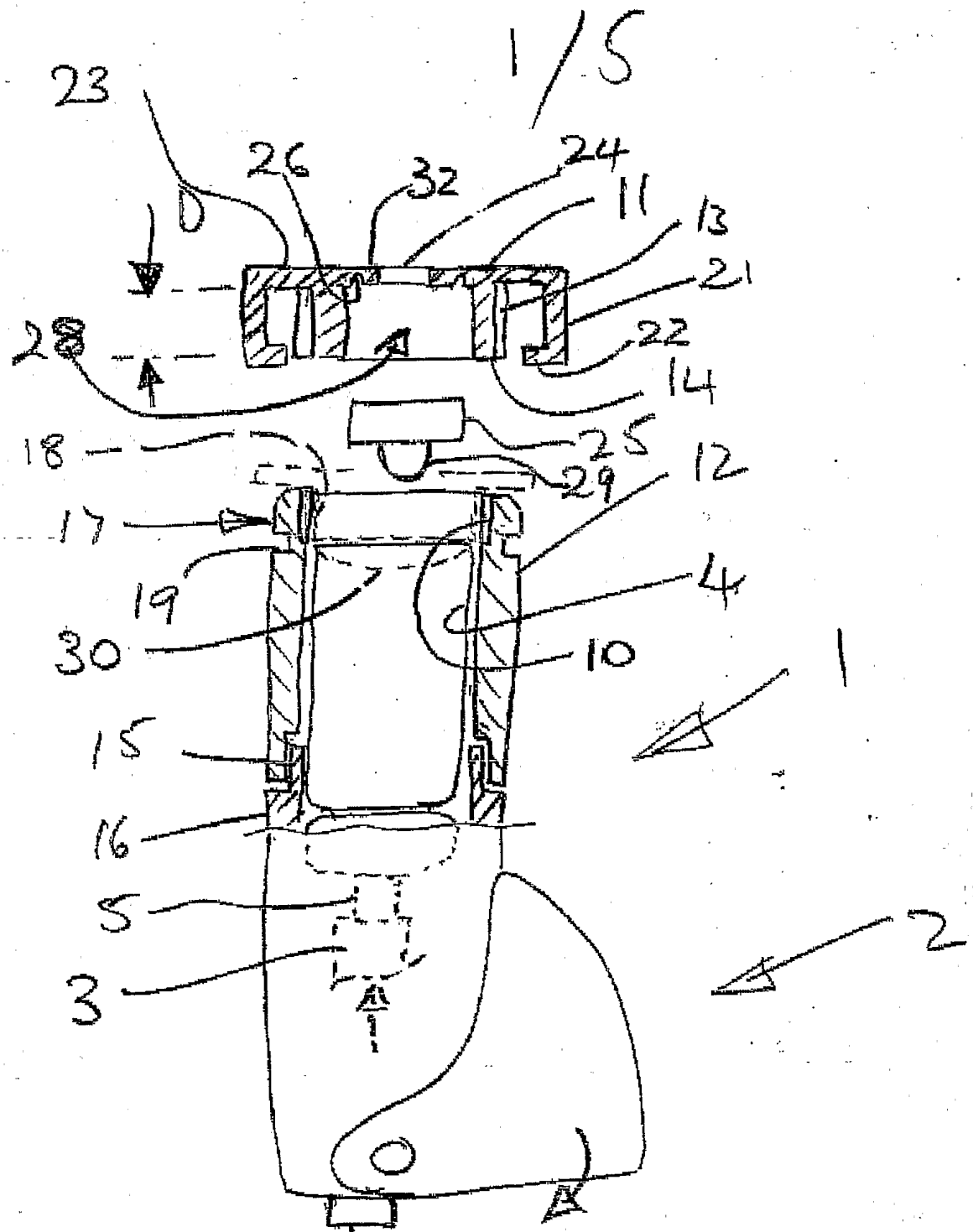
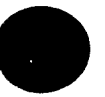


FIGURE 1





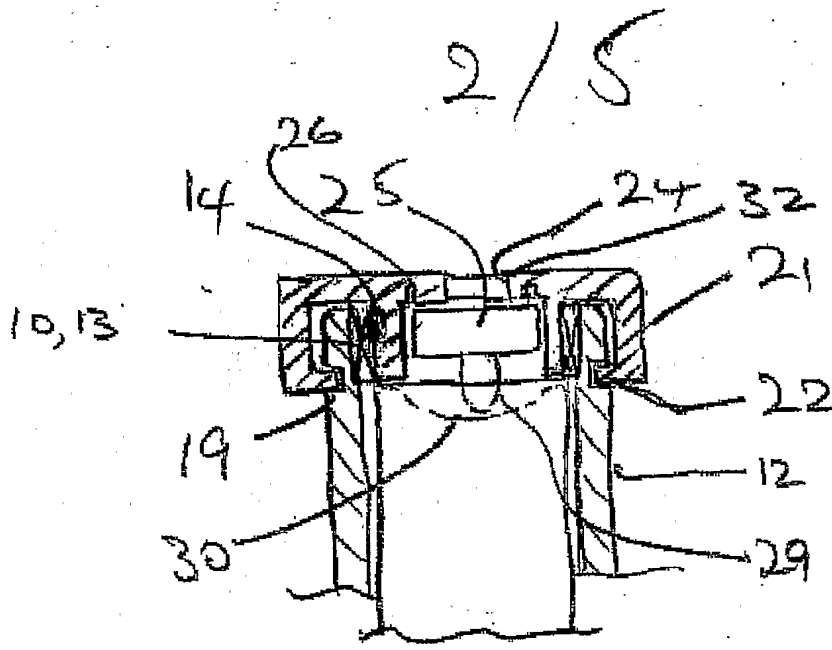


FIGURE 2

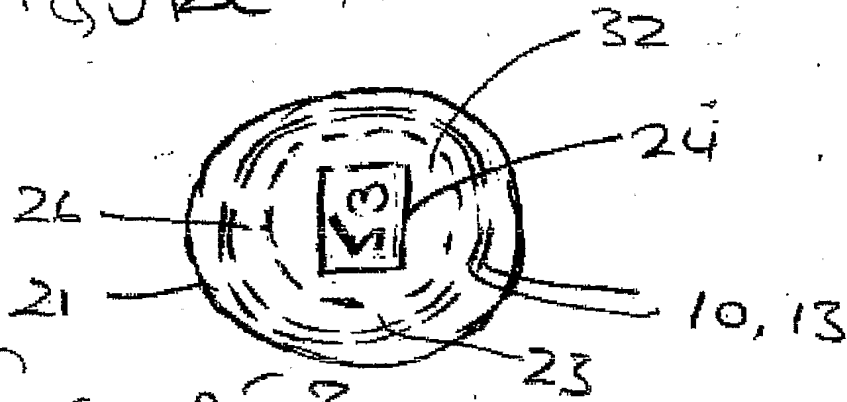


FIGURE 3

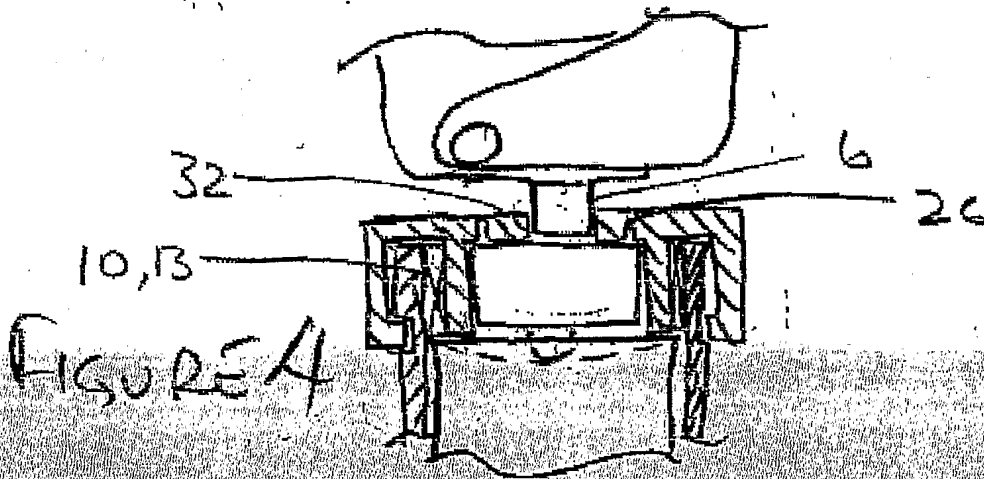


FIGURE 4



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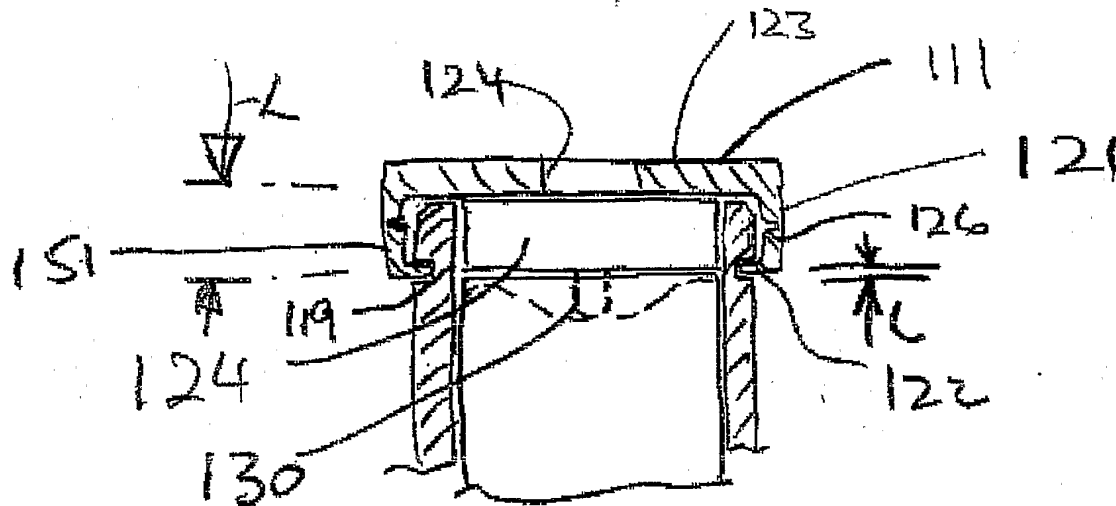


FIGURE 5

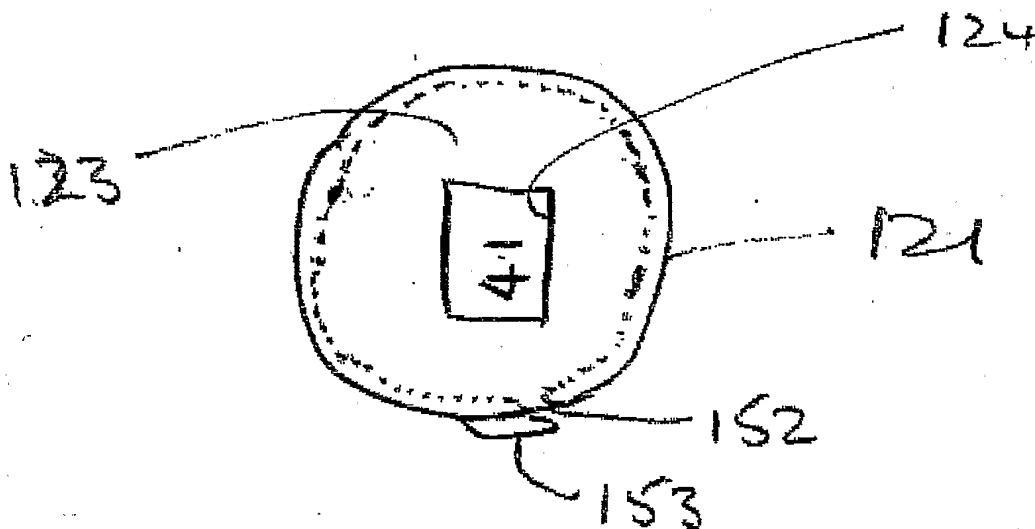


FIGURE 6



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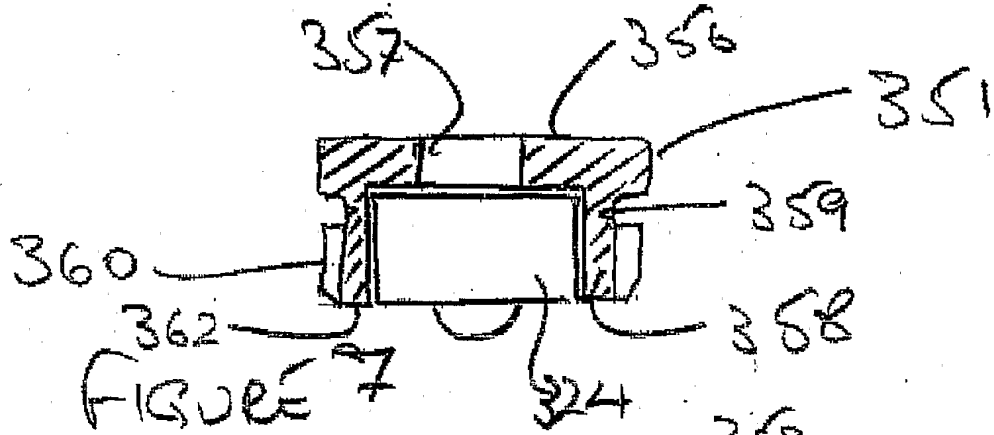
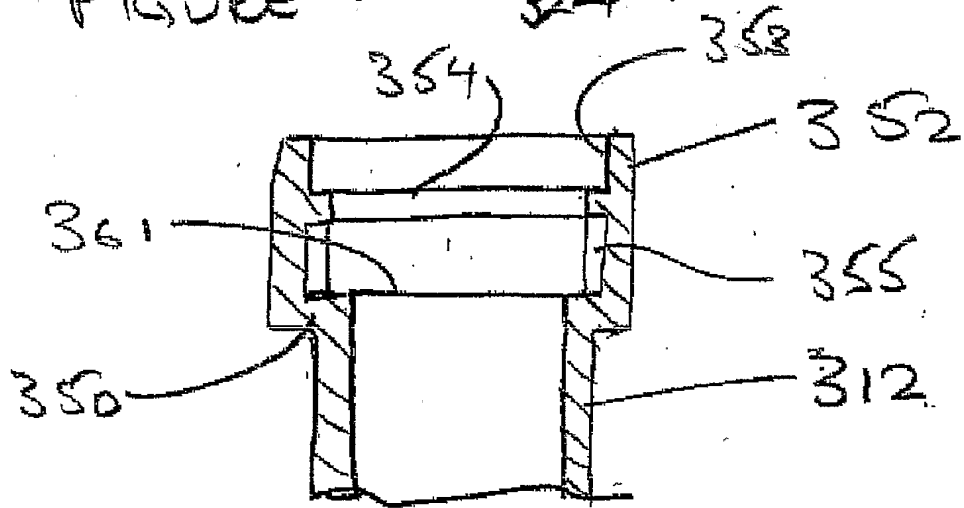


FIGURE 7



FIGURES

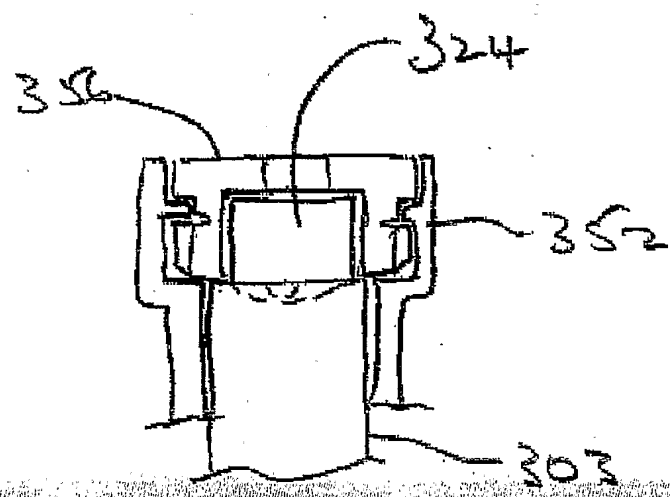


FIGURE 9



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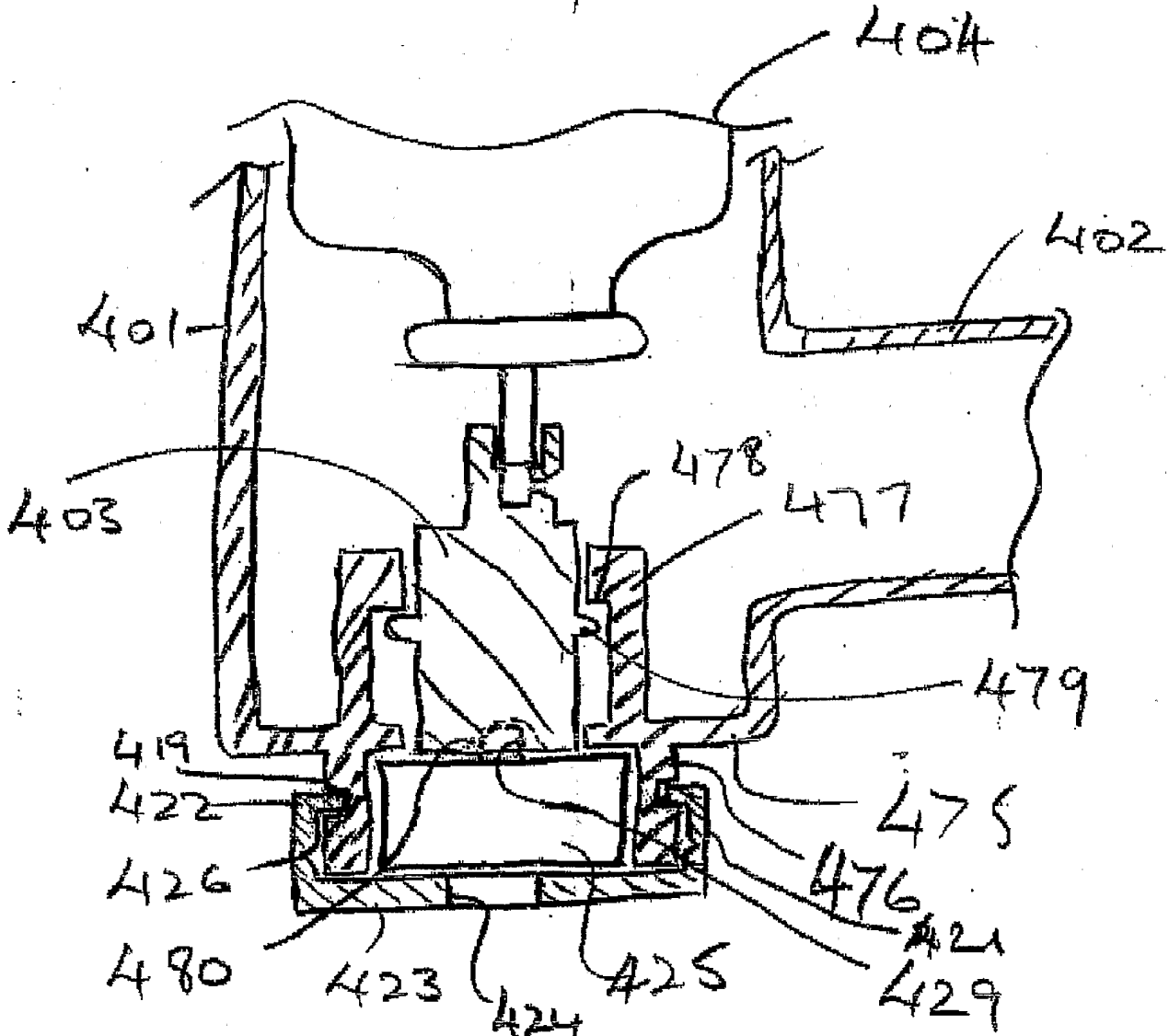


FIGURE 10



